02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 1 DEFINITIONS

Summary: As used in the board's rules, unless the context otherwise indicates, the following words have the following meanings:

[NOTE: Additional definitions are found in 32 M.R.S.A. §13702.]

Section 14-A of this chapter is adopted to read:

14-A. Drug administration clinic. "Drug administration clinic" is the administration of influenza or other vaccines identified in 32 MRSA §13831 on a mass basis at a scheduled event, with or without sign-up times, within or outside a retail pharmacy, rural health center or free clinic licensed under 32 MRSA §13751. "Drug administration clinic" does not include the administration of influenza or other vaccines to an individual on a walk-in or appointment basis at a retail pharmacy, rural health center or free clinic at any other time.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13723, 13835; PL 2009, c. 308

EFFECTIVE DATE:

No other changes are made to this chapter.

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 4-A ADMINISTRATION OF DRUGS AND IMMUNIZATIONS

Summary: This chapter sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the operation of drug administration clinics.

1. Minimum Requirements for Treatment Protocol Issued Pursuant to 32 MRSA §13833

For purposes of this section, a treatment protocol is a written collaborative agreement between a practitioner as described in 32 MRSA §13833 and a pharmacist who holds a certificate of administration or pharmacy as described in this section. A treatment protocol authorizes the administration of drugs and immunizations by a pharmacist who holds a certificate of administration pursuant to 32 MRSA §13831-13835 and must include, at a minimum, the following provisions:

1. Authorized Practitioner

The treatment protocol must state the name, professional title, license number and contact information of the authorized practitioner issuing the protocol.

2. Time Period

The treatment protocol must state the beginning and ending dates of the period of time during which the protocol will be in effect, and the date on which the treatment protocol was issued. The treatment protocol may not have a beginning date prior to the date of issuance.

3. Scope of Coverage – Pharmacists

The treatment protocol may cover specific, named pharmacists who hold a certificate of administration, or may cover on a blanket basis all pharmacists holding a certificate of administration who are employed by or under contract to a specific pharmacy or pharmacies. Thus, the protocol must either:

A. State the name and contact information of the individual pharmacists holding a certificate of administration who are covered by the treatment protocol; or

B. State the name and physical address of the pharmacy or pharmacies whose employee or contract certified pharmacists holding a certificate of

administration will be covered by the treatment protocol without further identification.

A treatment protocol that covers on a blanket basis all pharmacists who hold a certificate of administration and are employed by or under contract to a specific pharmacy or pharmacies only applies to the administration of drugs and immunizations by such pharmacists in the course of the pharmacists' employment or performance of contractual duties for a pharmacy identified in the treatment protocol.

4. Scope of Coverage – Drugs and Immunizations

The treatment protocol must identify the drugs and immunizations that may be administered pursuant to the protocol. For each drug and immunization named, the protocol must specify the maximum permitted dose and the route of administration. Only the following drugs and immunizations may be included in the treatment protocol:

Influenza vaccines, including intranasal vaccine
Pneumococcal vaccine
Shingles or herpes zoster vaccine
Tetanus-diptheria-pertussis vaccine
Tetanus-diphtheria vaccine
Booster tetanus-diphtheria vaccine

5. Standards for Observation

The treatment protocol must include standards for observation of the person receiving the drug or immunization to determine whether the person has an adverse reaction. The treatment protocol must specify a minimum post-administration patient retention period.

6. Adverse Reactions

The treatment protocol must include procedures to be followed by the pharmacist who holds a certificate of administration when administering epinephrine, diphenhydramine, or both, to a person who has an adverse reaction to an immunization administered by the pharmacist. The treatment protocol must include guidelines as to when contact with the local emergency services system or other follow-up health care providers is necessary or recommended.

7. Notification

A. The treatment protocol must require a pharmacist holding a certificate of administration who administers a drug or immunization pursuant to this treatment protocol to provide notice of the administration within 3 business days to the authorized practitioner who issued a prescription, treatment protocol or written standing order pursuant to 32 MRSA §13831(2) which authorized administration to the patient or to the patient population of which the patient is a member;

B. The treatment protocol must require a pharmacist who holds a certificate of administration to provide notice of an adverse reaction to a drug or immunization administered by the pharmacist of which the pharmacist is aware, including a statement as to whether epinephrine or diphenhydramine was administered, within 3 business days to:

(1) The authorized practitioner who issued the prescription, treatment protocol or written standing order which authorized administration to the patient or to the patient population of which the patient is a member;

(2) The Vaccine Adverse Events Reporting System co-sponsored by the Centers for Disease Control and the Federal Drug Administration; and

(3) The Maine Center for Disease Control and Prevention.

[NOTE: A prescription, treatment protocol or written standing order from an authorized practitioner is not required for administration of influenza vaccines.]

8. Submission to Board

The pharmacist holding a certificate of administration or the pharmacy or pharmacies to which the treatment protocol is issued shall submit a copy of the protocol to the board no later than 20 calendar days after the effective date of the protocol.

2. Administration Requirements

A pharmacist who holds a certificate of administration shall observe the following administration requirements in addition to requirements contained in:

- An applicable prescription, treatment protocol or written standing order issued pursuant to 32 MRSA §13831(2); and
- The applicable treatment protocol issued pursuant to 32 MRSA §13833 and Section 1 of this chapter.

1. Verification

A. For administration of influenza vaccines, the pharmacist who holds a certificate of administration shall verify as necessary that the patient is 9 years of age or older.

B. For administration of pneumococcal vaccine, shingles or herpes zoster vaccine, tetanus-diphtheria-pertussis vaccine, tetanus-diphtheria vaccine

or booster tetanus-diphtheria pursuant to a prescription, the pharmacist who holds a certificate of administration shall verify that the patient is the person to whom the prescription was issued.

C. For administration of pneumococcal vaccine, shingles or herpes zoster vaccine, tetanus-diphtheria-pertussis vaccine, tetanus-diphtheria vaccine or booster tetanus-diphtheria pursuant to a treatment protocol or standing written order, the pharmacist who holds a certificate of administration shall verify:

(1) That the patient is a member of the patient population (e.g., employee of designated employer, resident of designated municipality) covered by the treatment protocol or standing written order; and

(2) That the patient is 18 years of age or older.

2. Assessment

Prior to administering a drug or immunization, a pharmacist who holds a certificate of administration shall assess the patient for contraindications that would preclude vaccination.

3. Vaccine Information Statement

A pharmacist who holds a certificate of administration, prior to administration, shall give each patient or the patient's legal representative the appropriate vaccine information statement for the drug or immunization to be administered. The pharmacist shall orally review with the patient or patient's legal representative the portions of the statement describing the risks of the vaccination and what to look for and what to do in the event of a severe reaction.

4. Informed Consent

After providing the vaccine information statement, but prior to administration, the pharmacist who holds a certificate of administration shall obtain in writing the informed consent of the patient or the patient's legal representative to administration of the drug or immunization and to emergency administration of epinephrine, diphenhydramine or both if the patient has an adverse reaction to the drug or immunization administered.

5. Certificate of Immunization

A pharmacist holding a certificate of administration who administers a drug or immunization shall issue a certificate of immunization to the patient or patient's representative at the time the drug or immunization is administered. The certificate shall be signed by the pharmacist and shall include the patient's name,

date of immunization and the location where the drug or immunization was administered.

6. Record of Individual Administration – Influenza Vaccines

For influenza vaccines, including intranasal vaccine, the pharmacist who holds a certificate of administration shall record the administration in a computerized or non-computerized recordkeeping system that includes, at a minimum, the following information. The recordkeeping system may be a pharmacy's patient profile record system:

A. The name, date of birth, gender and contact information of the patient;

B. The name of the pharmacist holding a certificate of administration who administered the drug or immunization;

C. The written informed consent required by Section 2(4) of this chapter, or an electronic copy of the document;

D. The date of administration;

E. The street address or location of the building where the drug or immunization was administered;

F. The name of the drug or immunization administered, including the dose, route of administration, expiration date, manufacturer and lot number; and

G. In the event that epinephrine or diphenhydramine is administered pursuant to 32 MRSA §13831(3),

(1) The name of the pharmacist holding a certificate of administration who administered the drug;

(2) The date of administration;

(3) The street address or location of the building where the drug was administered; and

(4) The name of the drug administered, including the dose, route of administration, expiration date, manufacturer and lot number.

7. Record of Individual Administration – Non-Influenza Vaccines

For pneumococcal vaccine, shingles or herpes zoster vaccine, tetanus-diptheria-pertussis vaccine, tetanus-diphtheria vaccine or booster tetanus-diphtheria vaccine, the pharmacist who holds a certificate of administration shall record the administration in a computerized recordkeeping system that includes, at a

minimum, the following information. The recordkeeping system may be a pharmacy's patient profile record system:

A. The name, date of birth, gender and contact information of the patient;

B. The name of the pharmacist holding a certificate of administration who administered the drug or immunization;

C. The written informed consent required by Section 2(4) of this chapter, or an electronic copy of the document;

D. The date of administration;

E. The street address or location of the building where the drug or immunization was administered;

F. The name of the drug or immunization administered, including the dose, route of administration, expiration date, manufacturer and lot number;

G. For administrations authorized by prescription, the prescription;

H. For administrations authorized by a treatment protocol or standing written order, the name of the authorized practitioner who issued the treatment protocol or standing written order and the date of issuance; and

I. In the event that epinephrine or diphenhydramine is administered pursuant to 32 MRSA §13831(3) and the treatment protocol,

(1) The name of the pharmacist holding a certificate of administration who administered the drug;

(2) The date of administration;

(3) The street address or location of the building where the drug was administered; and

(4) The name of the drug administered, including the dose, route of administration, expiration date, manufacturer and lot number.

3. Operation of Drug Administration Clinics

1. Site Suitability

A drug administration clinic must be located in a sanitary, well-maintained, adequately-equipped space that is appropriately sized for the expected patient volume and facilitates interaction among clinic staff and patients.

2. Written Plan of Operation

The pharmacist holding a certificate of administration or pharmacy ~~who~~ that operates a drug administration clinic shall develop a written plan of operation prior to conducting the clinic, and shall ensure that the plan is complied with during operation. The plan must, at a minimum:

~~A. Identify the lead person or persons responsible for operation of the clinic and all pharmacists holding a certificate of administration, pharmacy technicians, student interns, other health care personnel and non-health care personnel who will staff or assist at the clinic;~~

~~B.~~A. Require that any non-health care personnel who assist at the clinic have no contact whatsoever with drugs, immunizations, needles or syringes;

~~C.~~B. Include a specific protocol for prevention of administration errors (e.g., administration of incorrect drug or incorrect dose to patient; administration of drug to wrong patient);

~~D.~~C. Include procedures for the orderly management and flow of patients through the clinic both pre- and post-administration;

~~E.~~D. Include a specific protocol for performing the following procedures required by Section 2 of this chapter:

(1) Verification (Section 2(1));

(2) Assessment (Section 2(2));

(3) Provision of vaccine information statement and discussion of possible adverse reactions (Section 2(3));

(4) Obtaining written informed consent (Section 2(4)); and

(5) Issuance of certificate of immunization (Section 2(5));

~~F.~~E. Incorporate the protocol for observing patients following administration required by Section 1(5) of this chapter. Clinic staff shall strongly recommend that all patients remain in the immediate vicinity of the vaccination site for the post-administration observation period specified in the treatment protocol. To facilitate patient compliance, the operator of the clinic shall make a comfortable sitting area available in the immediate vicinity of the administration site. The sitting area must be of adequate size and must be suitably equipped to accommodate the flow of patients for the full duration of the post-administration observation period;

~~G.~~F. Include a protocol for the safe storage and transportation of drugs and immunizations to ensure that the vaccine remains viable until the point of administration;

~~H.~~G. Include procedures to ensure that an adequate number of epinephrine and diphenhydramine syringes and other emergency medical supplies will be available for use in case a patient has an adverse reaction to the drug or vaccination administered; and

~~I.~~H. Include a protocol for infection control. Standard precautions to minimize the risks of spreading disease during vaccine administration must be in place. The protocol must include, at a minimum, the following provisions:

(1) *Handwashing.* Hands must be washed thoroughly with soap and water or cleansed with an alcohol-based waterless antiseptic between patients, before vaccine preparation or any time hands become soiled;

(2) *Gloving.* Gloves are not required to be worn when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on the hands. It is important to remember that gloves cannot prevent needlestick injuries;

(3) *Needlestick Injuries.* Needlestick injuries must be reported immediately to a lead person, with appropriate care and follow-up given. Safety needles or needle-free injection devices should be used if available to reduce the risk of injury;

[NOTE: For more information on needle-free injection technology, see the CDC website: http://www.cdc.gov/vaccinesafety/vaxtech/nfit/.]

(4) *Equipment Disposal.* Used needles may not be detached from syringes, recapped or cut before disposal. All used syringe/needle devices must be placed in puncture-proof containers to prevent accidental needlesticks and reuse. Empty or expired vaccine vials are considered medical waste and are subject to Chapter 900 of the rules of the Department of Environmental Protection, "Biomedical Waste Management Rules;" and

[NOTE: The operator of a drug administration clinic may be required to register as a biomedical waste generator with the Department of Environmental Protection.]

(5) *Vaccine Preparation.* Proper vaccine handling and preparation is critical in maintaining the integrity of the vaccine during transfer

from the manufacturer's vial to the syringe and ultimately to the patient.

3. Clinic Personnel

At the conclusion of a drug administration clinic the pharmacist holding a certificate of immunization or pharmacy that conducted the clinic shall attach to the written plan of operation for that clinic a list that identifies, by name and position:

A. The lead person or persons who were responsible for operation of the clinic; and

B. All pharmacists holding a certificate of administration, pharmacy technicians, student interns, other health care personnel and non-health care personnel who staffed or assisted at the clinic.

4. Retention of Records

Records received or created by a pharmacy or pharmacist pursuant to this chapter are subject to the record retention and production requirements of Chapter 24 of the board's rules.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13723, 13832, 13833, 13835; PL 2009, c. 308

EFFECTIVE DATE: